



PARKINSON'S DISEASE NEWS

<http://www.viartis.net/parkinsons.disease/news.htm>

1st December 2015 - News release

NUMIENT AUTHORISED FOR USE IN PARKINSON'S DISEASE

Impax Laboratories have received authorisation in the EU for the use of NUMIENT™ (Levodopa and Carbidopa) Modified-Release Capsules for the treatment of Parkinson's Disease. Numient is the same as Rytary, which is already available in the U.S.. Rytary and Numient are novel and distinct by including immediate release AND extended release versions of L-dopa. The different versions of Sinemet and Madopar include only immediate release OR extended release versions of L-dopa. For more information go to : <http://reference.medscape.com/drug/sinemet-rytary-carbidopa-levodopa-343043>

NUMIENT The authorisation is based on the results of Phase 3 clinical trials, which assessed the safety and efficacy in early and advanced Parkinson's Disease.

In the primary clinical trial, advanced Parkinson's Disease treatment with IPX066 (NUMIENT) reduced the "off" time, from 36% to 23% compared to 36% to 29% for immediate-release levodopa-carbidopa. IPX066 (NUMIENT) also increased the "on" time without dyskinesias during waking hours by 1.9 hours compared with an increase of 0.8 hours following treatment with immediate-release levodopa-carbidopa.

The most frequently reported adverse reactions were nausea, occurring in approximately 12% of all patients; then dizziness, headache, and dyskinesia, each occurring in approximately 8% of all patients; and insomnia, occurring in approximately 6% of all patients. Serious adverse events from gastrointestinal haemorrhage and allergic oedema were uncommon. For more information go to : <http://www.impaxlabs.com/>

<http://www.viartis.net/parkinsons.disease/news/151201.pdf>

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